No. 2024-1658

United States Court of Appeals for the Federal Circuit

UNITED THERAPEUTICS CORPORATION,

Appellant,

– v. –

LIQUIDIA TECHNOLOGIES, INC.,

Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE, 1:20-cv-00755, JUDGE RICHARD ANDREWS

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GLOSSARY

'793 patent	U.S. Patent No. 10,716,793
BB	UTC's Opening Blue Brief
FDA	Food and Drug Administration
IPR	*Inter Partes* Review
Liquidia	Appellee Liquidia Technologies, Inc.
PTAB	Patent Trial and Appeal Board
PTO	U.S. Patent and Trademark Office
RB	Liquidia's Responsive Red Brief
UTC	Appellant United Therapeutics Corporation

INTRODUCTION

Liquidia's response obfuscates the facts and misconstrues the law. Liquidia asserts that the '793 patent is "invalid" dozens of times—7 times in its two-page introduction alone—but repetition ad nauseam does not make that argument fact. No court or adjudicative body has ever held that the '793 patent is "invalid." To the contrary, this Court previously affirmed the district court's judgment of infringement and *no* invalidity.

Instead, the underlying act supposedly justifying the district court's decision on appeal is an administrative decision of "unpatentability," which remains subject to further appeal. But the difference between "invalidity" and "unpatentability" is dispositive here.

Liquidia simply assumes, without analysis or any stated rationale, that Article I "unpatentability" is the exact same as Article III "invalidity"—statute and controlling precedent be damned. Liquidia thus relies on an administrative determination that the patent's claims should be cancelled as "unpatentable"—a distinct concept arising from a different forum and decided upon a different burden of proof—to argue that the district court's discretionary modification of UTC's statutory remedy was proper. That is Liquidia's key point, and it is flatly wrong.

By statute and precedent, claims found unpatentable cease to exist only upon cancellation. *See* 35 U.S.C. § 318(b); *see also In re Bingo Card Minder Corp.*, 1998 WL 130514 (Fed. Cir. Feb. 25, 1998) (unpublished). Congress chose two paths to reach conclusions of invalidity and unpatentability, respectively, and those distinctions cannot be ignored.

Here, where the patent at issue was ruled by an administrative agency to be "unpatentable," the '793 patent remains in force. This Court previously affirmed a district court judgment that the '793 patent is not invalid, and the Patent Office does not cancel a patent until review is fully exhausted. And UTC's petition for a writ of certiorari of the unpatentability decision is currently pending. As a result, the infringed and not-invalid '793 patent continues to meet all the legal requirements entitling UTC to a statutory remedy under § 271(e)(4)(A) until the patent expires or ceases to exist via claim cancellation. The district court's purported exercise of "discretion" (RB2) to lift that statutory order was error.

It was also error for the district court to premise lifting that statutory order upon "issue preclusion" or "collateral estoppel." Appx4. The district court's final judgment was already affirmed, and the mandate issued. Liquidia misunderstands this Court's straightforward law on

finality for purposes of issue preclusion. As a matter of law, the district court case was neither "pending" nor "co-pending" at the time the PTAB's unpatentability case was affirmed. Once this Court's mandate issued on October 3, 2023—fully affirming the district court and not remanding any issues—that decision became immune to issue preclusion under *Fresenius*. No case Liquidia cites says otherwise.

Accordingly, UTC is entitled to retain its duly awarded and affirmed statutory relief—the § 271(e)(4)(A) order preventing Liquidia's 505(b)(2) approval—for a limited period of time: until expiration of the infringed '793 patent or until that patent ceases to exist via claim cancellation. Because neither of those statutorily defined events has yet occurred, this district court's order must be reversed.

Liquidia also cannot escape this statutory result based on a Rule 60 plea in equity when it is the natural result of its strategic litigation decisions. Liquidia intentionally chose to pursue its obviousness challenges to the '793 patent in an Article I agency proceeding. Liquidia did so knowing that the statute makes clear that no unpatentability decision takes effect until all appeals are exhausted and the PTO's issues a certificate. Liquidia's attempted shortcut violates UTC's statutory patent rights, its

procedural appellate rights, and its right under the Hatch-Waxman framework to a mandatory statutory order upon proving that the '793 patent was both infringed and not invalid in district court. The district court provided no basis for granting Liquidia's Rule 60 motion except for the erroneous belief that the '793 patent had been held "invalid" and that issue preclusion compelled granting Rule 60 relief. Because those conclusions are legally erroneous, the district court's decision must be reversed.

ARGUMENT

I. UTC is entitled to a § 271(e)(4)(A) order preventing FDA approval so long as the '793 patent is unexpired and not "invalid."

No court has determined that the '793 patent is "invalid." Despite this plain fact, Liquidia repeatedly states that "[t]he '793 patent is invalid." RB5, 9; RB1 ("it is invalid"); RB13 ("the '793 patent has been invalidated"); *see also* RB20, 22, 23, 25, 31, 34. Liquidia goes so far as to characterize the PTAB's decision as finding the "claims of the '793 patent *invalid*" and this Court's decision as "affirm[ing] the *invalidity* ruling." RB4 (emphasis added). Just saying that the '793 patent has been "invalidated" does not make it true.

Instead of invalidity, the PTAB's FWD found that the claims "of the '793 patent are *unpatentable*." Appx4344 (emphasis added); *see also*

Appx4299-Appx4347. That FWD was affirmed on appeal, and this Court made clear that it affirmed "the Board's *unpatentability* determination." Appx4297 (emphasis added); *see also* Appx4285-Appx4297. Liquidia's oversight of the differences between these two distinct concepts is fatal to its arguments.

A. "Invalidity" and "unpatentability" are not the same.

The distinction between an "invalidity" finding and an "unpatentability" finding is meaningful, not just semantic. It reflects distinctions between the processes by which parties can challenge patents, indicates the tribunal that ruled on a patent challenge, and affects if and when a decision in a parallel proceeding can have an impact on other proceedings or FDA approval.

"Invalidity" is adjudicated by an Article III court. District court patent challenges by nature involve already-issued patents, and each patent is presumed "valid." 35 U.S.C. § 282(a); ("The burden of establishing *invalidity* . . . shall rest on the party asserting such *invalidity*." (emphasis added)); *see also Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011) ("[A]n invalidity defense [must] be proved by clear and convincing evidence."). Indeed, "invalidity" defenses in patent cases are defined by

statute. 35 U.S.C. § 282(b)(2)-(3). And as this Court has explained, "in the litigation context, validity, rather than patentability, is the issue." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1080 n.7 (Fed. Cir. 2012).

"Unpatentability," by contrast, is determined by the PTO. *See id.*; *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1307 (Fed. Cir. 2017) (observing that "'unpatentability' . . . may refer to either pending or issued claims"); *see also* MPEP § 2100 (entitled "Patentability"); MPEP § 2103, § I. (explaining that applications and proposed claims must be reviewed "for compliance with every statutory requirement for patentability"). The statute also defines IPR as involving unpatentability, stating that a "petitioner . . . may request to cancel as unpatentable 1 or more claims of a patent," and if review is instituted, the PTAB must issue a "final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d)." 35 U.S.C. §§ 311(b), 318(a). Section 318(b) requires, after the time for appeals, publishing a certification canceling any claims found "unpatentable." 35 U.SC. § 318(b). UTC's examples, including *Return Mail* and analogous statutory frameworks, demonstrate that the "Patent Office has

decisively interpreted § 318(b)'s mandate to require that it not cancel a patent until 'any appeal has terminated' as including final adjudication by the Supreme Court." BB21-24.

Liquidia complains that UTC's "examples do not establish the validity of the patent at issue until cancelation occurs," but it fails to explain why the Patent Office's statutory interpretation of § 318(b) would be different for UTC than Return Mail. RB18. Notably, Liquidia did not point to any counter statements from the PTO where it interpreted its statutory authority as permitting claim cancellation prior to conclusion of all appeals, including Supreme Court review. As far as UTC is aware, none exist. The PTO's statements are persuasive evidence that the '793 patent continues to exist and is not "invalid" as Liquidia baldly asserts. Because the statute is explicit, the PTO will only cancel the claims of the '793 patent if UTC's appeal to the Supreme Court is unsuccessful.

Thus, "invalidity" and "unpatentability" reflect differences between the methods for challenging patents and the resulting types of rulings, which arise under different statutory frameworks and have different burdens of proof, decision makers, and procedures.

The Hatch-Waxman statute recognizes this crucial distinction between unpatentability and invalidity. When, as here, the district court has found infringement and that judgment is affirmed, FDA may only approve an application when the patent expires, i.e., "on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35." 21 U.S.C. § 355(c)(3)(C)(ii)(II). Alternatively, "if the judgment *of the district court* is appealed," the approval will be made effective on "the date on which the court of appeals decides that the patent is *invalid*." 21 U.S.C. §§ 355(c)(3)(C)(i), (ii)(I), (ii)(I)(aa) (emphasis added). Thus, the Hatch-Waxman statute defines affirmance of a *district court invalidity* decision—which does not apply here—as the key time point.

Liquidia's rebuttal to this point (RB19) misrepresents § 355(c)(3)(C)(ii)(I)(aa) as blanketly permitting FDA approval "upon this Court's determination of invalidity," implying that it even covers PTO unpatentability decisions. That is misleading and wrong. This subsection by its own terms only involves appeals *from district court*. *See* 21 U.S.C. § 355(c)(3)(C)(ii)(I)(aa) (stating "if . . . the district court decides that the patent has been infringed . . . [and] if the judgment of the district court is appealed, the approval shall be made effective on . . . the date on which

the court of appeals decides that the patent is invalid or not infringed"). Liquidia fails to cite any similar statute addressing PTO appeals.

Thus, § 318 governs the resolution of the IPR process. It requires a certificate cancelling claims only after "any appeal has terminated." 35 U.S.C. § 318(b). Liquidia disregards the differences between "invalidity" and "unpatentability" as well as the statutory framework that consistently delineates between the two, but the plain language of the statutes defeats Liquidia's arguments. *See United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 240-41 (1989) ("[A]s long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute."). Liquidia is not entitled to any remedy other than the one it sought—cancellation. *Middlesex Cnty. Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 14-15 (1981) ("[W]here a statute expressly provides a particular remedy," courts "must be chary of reading others into it.").

Lacking statutory support, Liquidia cites a straw man instead, asserting that "[f]ollowing UTC's rationale, . . . the district court would have been required to enjoin Liquidia under the '066 patent because it was infringed." RB16. This argument fails for the same reason as

Liquidia's others, as it again overlooks the distinction between invalidity decided by a district court and unpatentability decided by the PTAB and ignores statute.

Under § 355, when a district court makes an invalidity decision, FDA may approve an application when the *court* enters judgment. 21 U.S.C. § 355(c)(3)(C)(i) (when a "district court decides that the patent is invalid or not infringed . . . the approval shall be made effective on (I) the date on which *the court* enters judgment reflecting the decision" (emphasis added)). There was no requirement for the district court to "enjoin Liquidia under the '066 patent because it was infringed"—and UTC has never argued as much—because the same district court decision found the patent invalid. Appx3624. In fact, the district court's treatment of the '066 patent supports UTC's reading of the statutory scheme. Consistent with § 355, the district court entered judgment of invalidity and noninfringement with no statutory impediment (i.e., § 271(e)(4)(A) order) to FDA approval.

B. The elements of § 271(e)(4)(A) remain in place, mandating UTC's statutory remedy.

Liquidia cannot escape the plain text of the statute. This is a Paragraph IV case triggered by Liquidia's filing of its 505(b)(2) application.

See 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(c)(3). That means that once UTC proved in district court that its Orange Book-listed patent was infringed[1] and Liquidia failed to prove it invalid by clear and convincing evidence, there could only be one remedy: an order to FDA not to approve Liquidia's product during the life of the listed patent. The district court found both requirements met, and that judgment was affirmed. Appx4108. The statute makes clear that the mandatory FDA order remains undisturbed by operation of law until patent expiration, the only exception being the narrow circumstance where the legal basis for the statutory order (i.e., the infringed '793 patent) ceases to exist. *See* BB13-15, 18-24; *see also Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1334 (Fed. Cir. 2013) ("[C]ancellation extinguishes the underlying basis for suits based on the patent.").

Given that infringement is undisputed (and indisputable), the district court improperly ignored that use of the word "shall" in the statute

[1] Liquidia's argument regarding the "relevant" act of infringement (RB14-15) is a non-sequitur. Whether the "relevant" act of infringement giving rise to Hatch-Waxman statutory relief under § 271(e)(4)(A) is the filing of the 505(b)(2) application or Liquidia's infringement under § 271(a), (b), or (c), it is undisputed that the district court found that Liquidia will induce infringement.

"generally imposes a nondiscretionary duty" and mandates that the remedy continue so long as there is "a patent that has been infringed." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018) (citing *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)). The term "shall" gave the district court no discretion after finding infringement and no invalidity, and Liquidia has cited no statute modifying that "shall" to allow for discretion after entry of the FDA order. In fact, the district court did exactly what the Supreme Court prohibited when it said it "need not and will not invent an atextual explanation for Congress's drafting choices when the statute's own terms supply an answer." *Id.* at 1357.

Neither the district court nor Liquidia provides any supporting authority for its atextual interpretation of § 271(e)(4)(A) allowing the district court to undo UTC's statutory remedy. Instead, Liquidia argues that the '793 patent is "invalid," thus undermining the basis for the statutory order. RB16 ("[I]n order to enter an injunction, a valid patent must be infringed."). That argument fails for the reasons discussed above: the '793 patent was found unpatentable by an administrative agency, and even though that decision was affirmed by this Court, it was not found

"invalid." *Supra* pp. 4-10. And because the patent claims were found "unpatentable" but have not been cancelled, any modification of the court's § 271(e)(4)(A) order is premature.

Cancellation is not, as Liquidia contends, a mere "ministerial formality." RB17-18. That view is contrary to law. Indeed, this Court has held that a patent claim rejected as unpatentable in a reexamination proceeding was still a valid patent that supported jurisdiction for an infringement action in the district court because the PTO had not yet cancelled the claims. *Bingo Card*, 1998 WL 130514, at *1; 35 U.S.C. § 307(a). The Court explained that "[b]efore the courts, a patent is presumed valid and it remains so until 'it is no longer viable as an enforceable right,'" and that "[a] claim is not canceled until the Board acts and the Commissioner cancels the claim." *Id.* at *2.

Liquidia's cases are inapposite. *Security People* relates to administrative finality for purposes of judicial review (*Sec. People, Inc. v. Iancu*, 971 F.3d 1355, 1360-61 (Fed. Cir. 2020)), but whether agency action is "final" enough to warrant judicial review is not at issue here. Of course this Court can review PTAB decisions before the certificate of cancellation—indeed, that is consistent with the statute's requirement to issue

the certificate only *after* "any appeal[s]" have concluded. 35 U.S.C. § 318(b). Liquidia also argues that the *XY* court "did not wait for claim cancellation." RB17-18 (citing *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1294 (Fed. Cir. 2018)). *XY* does not apply here either, however, because it involved co-pending cases, whereas this case does not. *Infra* pp. 16-21.

Instead of a mere "formality," a certificate of cancellation is an important event that marks the end of the statutory process that defines the "second look" at patentability. *Cuozzo Speed Techs., LLC v. Comm. for Intell. Prop.*, 579 U.S. 261, 279 (2016). Even if Liquidia argues the issuance of the certificate can be said to be a formality *once all appeals have concluded*, the conclusion of appellate review is decidedly *not* a formality, which is why the certificate must wait until after that process concludes. And there is certainly no reason to act as if the certificate has already issued when it may never issue.

Liquidia's other cases are also distinguishable. RB10. Liquidia argues that the '793 patent can no longer provide the basis for a § 271(e)(4)(A) order, but in each of the cases Liquidia cites, an Article III court either found the patent invalid (rather than unpatentable), waited

for claim cancellation prior to lifting the injunction, or applied issue preclusion to a pending case. *ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1349 (Fed. Cir. 2015) (applying issue preclusion and lifting injunction after claim cancellation); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1578 (Fed. Cir. 1994) (applying issue preclusion after claims were adjudicated invalid by an Article III court); *U.S. Ethernet Innovations, LLC v. Tex. Instruments Inc.*, 645 F. App'x 1026, 1029-30 (Fed. Cir. 2016) (same); *John Simmons Co. v. Grier Bros. Co.*, 258 U.S. 82, 87 (1922) (same). Because issue preclusion is not available (*see infra* pp. 16-27), the '793 patent was found "unpatentable," and the claims have not yet been cancelled—and may never be—the statutory remedy must remain in place.

II. The district court's decision to grant Rule 60 relief misapplied the law of issue preclusion.

The district court rested its conclusion that "Liquidia is entitled to modification of the final judgment" on the premise that "'an affirmance of an invalidity finding, whether from a district court or the [PTAB], has a collateral estoppel effect on' the present case." Appx4 (quoting *XY*, 890 F.3d at 1294) (alteration in original). Liquidia argues the same. RB25. Yet the district court misapplied the black letter law of issue preclusion

(Appx1-Appx5), which requires identical issues and burdens of proof and a pending (non-final) case before it can be applied. *See* BB25-33.

A. The district court's infringement judgment was final and immune from issue preclusion.

As explained in UTC's opening brief, once this Court's mandate issues, a district court case becomes final for purposes of immunity to issue preclusion. *See, e.g.*, BB26-28; *Fresenius*, 821 F.3d at 1341 (final judgments with no issues left to resolve are "immune to the effect of [a later] final judgment in [] PTO proceedings"); *see also id.* at 1340-41 (distinguishing different types of finality). *Fresenius* and *Packet* explain that (i) a judgment becomes immune to issue preclusion after a Federal Circuit mandate leaves "nothing for the court to do but execute the judgment" and (ii) a determination of unpatentability becomes capable of supporting issue-preclusion only after it is affirmed by this Court. *Fresenius*, 721 F.3d at 1341; *Packet*, 100 F.4th at 1383, 1386.

The timing of both issues precludes the application of issue preclusion here. The district court's infringement judgment was affirmed and the mandate issued on October 3, 2023. Appx4108-Appx4132 (October 3, 2023 district court appeal mandate issuance). That affirmance and mandate left "nothing for the court to do but execute the judgment." *Packet*,

100 F.4th at 1383. The case was done. Trial was complete, the district court issued its order, Liquidia appealed and lost, and the mandate issued. Unlike the non-final judgments in *Fresenius*, *Packet*, and *ePlus*, there were no outstanding issues to resolve—no undetermined royalties on infringing products, modifications to a compensatory damages award, or adjustments to a list of enjoined products. *See Fresenius*, 721 F.3d at 1341; *Packet*, 100 F.4th at 1383; *ePlus*, 789 F.3d at 1353. Indeed, here the lower court's judgment was completely affirmed, and because relief was mandated by statute and monetary damages were not at issue, there were no remaining questions concerning the "scope of relief." *Fresenius*, 721 F.3d at 1341.

It was not until December 20, 2023—two-and-a-half months later—that the PTAB's determination of unpatentability was affirmed. Appx4285-Appx4297 (December 20, 2023, PTAB affirmance). This was too late: the previous infringement rulings had become final and immune from issue preclusion under *Fresenius*.

Liquidia's response makes several flawed arguments. First, Liquidia misconstrues UTC's position as contending that a judgment becomes "'immune' from Rule 60(b) relief." RB20. But UTC made no such

argument. As UTC's opening brief explains, the judgment was "immune" *from the application of issue preclusion*—not immune to everything—under the finality timing scheme set forth by this Court in *Fresenius*. *Fresenius*, 721 F.3d at 1341; *Packet*, 100 F.4th at 1383.

Liquidia's argument demonstrates its fundamental misunderstanding of the difference between issue preclusion, which applies only to *pending* or *subsequent* actions, and Rule 60, which may provide relief from a final judgment after the case is no longer pending. *Compare Packet*, 100 F.4th at 1386 (an "affirmance of the Board's determination of unpatentability . . . 'has an immediate issue-preclusive effect on any *pending or co-pending* actions involving the patent'" (emphasis added)), *with Kuri v. Bergen Cnty.*, 137 F. App'x 437, 440 (3d Cir. 2005) ("A court always had the power to modify earlier orders in a *pending* case," so "Rule [60] was devised to give the district court a power of revisitation [for final, non-pending cases] it had lacked." (emphasis added)).

Second, Liquidia asserts that none of UTC's cases apply because they relate to monetary damages. But there is no basis to ignore this Court's case law based on the remedy involved. Here, the court was required to issue a § 271(e)(4)(A) order, and did so, just like previous parties

were obligated to pay damages, and did. Liquidia posits that a case can never be final if it involves "prospective" relief. *See* RB22. *Fresenius* and its progeny do not go so far. Rather, these cases explain that the finality question is a simple one: "is there, post-mandate, anything left to do other than execute the judgment?" *Packet*, 100 F.4th at 1385. If the answer is no, then the case is final. *Id.* While unresolved questions regarding the "appropriate scope" of prospective relief may render a case non-final, the mere existence of prospective relief itself cannot. *ePlus*, 789 F.3d at 1359 (vacating injunction after formal patent cancellation where, post-mandate, there was a "substantial question as to the appropriate scope of the injunction," i.e., which products and activities it should cover). Indeed, *ePlus* indicates that a prospective remedy is final unless its propriety or scope are at issue following appeal:

> [B]ecause the propriety of the injunction against sales and manufacturing was still an issue after the first appeal, there had not been "a final decree . . . that finally adjudicates upon the entire merits, leaving nothing further to be done except the execution of it." And the "scope of relief re-main[ed] to be determined. . . ." *The injunction was not final* and under Worden, the cancellation of the claim by the PTO required that the injunction and contempt sanctions be vacated.

Id. at 1361 (internal citations omitted) (emphasis added). Here, the scope and propriety of UTC's remedy were mandated by § 271 and were not at issue post-mandate. Even under the cases relied upon by Liquidia, the infringement judgment here was final and immune from issue preclusion based on the subsequently affirmed PTAB decision. The district court thus erred in concluding that the PTAB affirmance has retroactive issue-preclusive effect on UTC's § 271(e)(4)(A) relief.

Lastly, in a strained attempt to identify *some* outstanding issue allegedly existing after this Court's mandate issued to the district court, Liquidia argues that the judgment was not final in view of its pending motion to stay enforcement of the judgment "pending appeal" because there were "other, substantive matters to resolve." RB23. But a motion to stay is not a substantive motion on the merits, it is merely a request to delay a judgment that has already been substantively decided. Thus, Liquidia's motion only confirms that the case was already final. And an "insubstantial issue" is insufficient to keep a case alive. *Packet*, 100 F.4th at 1387. Further, Liquidia's motion was filed on September 9, 2022, and denied on December 15, 2023. Thus, by the time the IPR decision was affirmed on December 20, 2023, the motion to stay no longer could make

the case still pending (if it ever did). *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 2023-1805, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023). Liquidia points to no other issue allegedly outstanding after that denial. RB23-24.

B. Liquidia only relies on "non-final" authority to establish the propriety of applying issue preclusion to the patent owner.

Liquidia argues that Federal Circuit precedent "establishes the propriety of applying collateral estoppel to the patent owner." RB27-28. This is a red herring and demonstrates Liquidia's misunderstanding of the issues raised in UTC's appeal. Not once did UTC assert that issue preclusion can *never* be used against a patent owner to preclude re-litigation. Rather, the issue at hand is whether issue preclusion can be applied to unwind a case that has been rendered final by this Court's mandate based on an administrative agency decision involving non-identical issues and different burdens of proof. *See* BB11. It cannot. *See* BB25-33; *XY*, 890 F.3d at 1300 (Newman, J., dissenting in relevant part) ("[T]he different standards of validity in the PTAB and the district court, the different burdens of proof, and the different standards of appellate review in this court . . . all weigh[] heavily against estoppel."); *see also Grogan v.*

Garner, 498 U.S. 279, 284-85 (1991) (reasoning that issue preclusion cannot apply to an issue that must be proven by clear and convincing evidence where the prior decision on that issue was governed by the preponderance-of-the-evidence standard of proof).

It is well-settled that, "in general, when a claim is *cancelled*, the patentee loses any cause of action based on that claim, and any pending litigation in which the claims are asserted becomes moot." *Fresenius*, 721 F.3d at 1340 (emphasis added). In *Fresenius*, the PTAB's finding of unpatentability in a reexamination proceeding and subsequent cancellation of claims mooted a district court judgment that was not "final" because the litigation had not been "entirely concluded." *Id.* at 1341, 44.[2] So too in *ePlus*: the injunction had to be lifted only after the reexamined patent claim was actually cancelled. 789 F.3d at 1351, 1354.

[2] To be clear, *Fresenius* was not based on issue preclusion. Instead, it was based on mootness. 721 F.3d at 1340, 45 ("The latter is binding not because of collateral estoppel, but because Congress has expressly delegated reexamination authority to the PTO under a statute requiring the PTO to cancel rejected claims, and cancellation extinguishes the underlying basis for suits based on the patent."). Regardless of which legal doctrine applies (issue preclusion or mootness), the district court here did not apply the black letter law of either.

Liquidia asserts that *XY* and *Prism* support the "*immediate*[]" application of collateral estoppel. RB10-11. Neither case compels that result. In *XY*, the invalidity affirmance issued while the first case was still pending on appeal; this case was no longer pending. *Prism* is a non-precedential opinion and involved an affirmed judgment of a district court's finding of *invalidity*.[3] *Prism Techs. LLC v. Sprint Spectrum L.P.*, 757 F. App'x 980, 982 (Fed. Cir. 2019). By contrast, this case involves an agency *unpatentability* determination. This Court in *Prism* only granted relief because an affirmed judgment of invalidity is "'an act which, in judgment of law, extinguishes the patent' claims, *akin for present purposes to a cancellation of those claims*, after which they 'can no more be the foundation for the assertion of a right.'" *Id.* at 987–88 (emphasis added). *Prism* does not support Rule 60 relief where, as here, there has been no "act which . . . extinguishes the patent claims"—i.e., cancellation. *Id.*

The cases cited by Liquidia and its reference to UTC's assertion of the '793 patent in a second litigation do not suggest otherwise. So long as

[3] Liquidia also asserts that "the Court had previously affirmed the district court's decision that Sprint infringed." RB11. That is incorrect. The *Sprint* case involved a jury finding of infringement and infringement was not addressed on appeal. *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360 (Fed. Cir. 2017).

the requisite elements are satisfied, non-final, a patent infringement claim in pending litigation can be precluded by an affirmance of a decision finding patent claims unpatentable (*see supra* pp. 16-19); but a final judgment of infringement and § 271(e)(4)(A) order can only be unwound by patent expiration or cancellation (*see supra* pp. 22-23). UTC voluntarily dismissed without prejudice a '793 patent infringement claim against Liquidia in another case (*United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 23-cv-975, D.I. 17 (D. Del. Jan. 22, 2024)), but that case was still pending. Unlike here, there was no final judgment at all, let alone one affirmed by this Court with an issued mandate. Likewise, in *Ohio Willow*, the case was still pending. Issue preclusion was applied to preclude re-litigation of the validity of claims that were "substantially similar" to those that were adjudicated invalid in a separate district court proceeding. 735 F.3d at 1341-43. But issue preclusion was applied at the summary judgment stage, and thus re-litigation was precluded before the case had ever been appealed and certainly before a mandate was ever issued by a court of appeals. *Id.*

Similarly, while the *Nuvo Pharmaceuticals* court unwound a district court's judgment, it did so on direct appeal before any court of

appeals' affirmance and before any mandate had ever issued. 774 F. App'x at 679. The facts of *O2 Micro* are no different. There, this Court vacated the lower court's judgment of infringement on direct appeal—before any mandate had issued—due to the Federal Circuit's same-day invalidity decision in a companion proceeding regarding the same patent. 315 F. App'x at 266. Again, in *Pharmacia*, issue preclusion was applied by the district court on summary judgment to preclude the patent owner's assertion of infringement based on invalidity and unenforceability rulings in a separate district court proceeding involving the same patent, and this Court simply affirmed on direct appeal. 170 F.3d at 1375, 1379-82.

Finally, on direct appeal in *Mendenhall*, this Court reversed judgments of infringement in two non-final cases based on issue preclusion due to the Federal Circuit's affirmance of invalidity in a separate proceeding involving the same patents. 26 F.3d at 1576-78.[4] Therefore,

[4] *Mendenhall* was a consolidated appeal of two district court actions, one involving Barber-Green and another involving Astec. 26 F.3d at 1577. The *Barber-Green* case was a direct appeal from the district court's infringement finding and awards of damages and injunctive relief. *Id.* The *Astec* case was a direct appeal from the district court's decision regarding

under *Fresenius* and its progeny, each of the cases cited by Liquidia were non-final when presented to this Court for review and thus eligible for the application of issue preclusion. Liquidia has not cited any support for the district court's unprecedented decision to unwind a judgment using issue preclusion that has been rendered final by this Court's mandate.

* * *

While it may be true that "[a] continuing decree of injunction directed to events to come is subject always to adaptation as events may shape the need" (*ePlus*, 789 F.3d at 1355), that "adaptation" cannot be achieved under the guise of issue preclusion here because the judgment was already final.[5] Because issue preclusion is unavailable, Liquidia must instead demonstrate that it is otherwise entitled to relief under Rule 60. Liquidia has not done so. Liquidia's Rule 60 motion and the

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issue preclusion and damages only. *Id.* This Court previously affirmed the *Astec* court's earlier judgment of no invalidity in a separate interlocutory appeal. *Id.* at 1576-77. Because "the *Astec* case was still pending before the Tennessee district court for determination of damages and other issues," it was not yet final when the *Mendenhall* court applied issue preclusion. *See id.* at 1576.

[5] The issues and burdens of proof in the two proceedings are also different. BB33. As previously explained, Liquidia did not present obviousness defenses at trial, so there were no issues in common between this district court litigation and the '793 patent IPR. BB29-33.

district court's order improperly apply *XY*'s timing of issue preclusion (which applies immediately to any pending or co-pending actions after affirmance of an unpatentability determination) to its request for Rule 60 relief from a final judgment (which is not available unless and until the patent is cancelled).

III. Liquidia is not otherwise entitled to relief because the circumstances giving rise to its Rule 60 motion are attributable to its own strategic decisions.

Ackermann makes clear that Rule 60(b) may not be invoked to rescue litigants from their own "free, calculated, [and] deliberate" choices when hindsight reveals that those decisions had unwanted consequences. *Ackermann v. United States*, 340 U.S. 193, 198 (1950); *see also Ehrheart v. Verizon Wireless*, 609 F.3d 590, 595-96 (3d Cir. 2010) (noting that "[t]he choice to settle implicitly acknowledges calculated risks and . . . [w]e will not relieve a party of that decision"). Liquidia elected to drop its § 103 defenses from the district court case from which it now seeks relief and instead made those arguments before the PTAB. Favoring the lower burden of proof in IPR proceedings before the PTAB, Liquidia risked the situation it now faces: affirmance of the district court's judgment and

mandate issuance by this Court before the PTAB's determination could have any preclusive effect.

As explained above, a PTAB finding of unpatentability has no issue preclusive effect on a district court judgment that has been rendered final by a Federal Circuit mandate. *Supra* pp. 16-21. Liquidia could have avoided this problem by litigating the § 103 issues at the district court in one proceeding, risking preclusion in the PTAB from an adverse ruling, and bearing a clear and convincing evidence burden of proof. But it chose not to take that gamble. Rule 60(b) cannot be used to "rescue a litigant from strategic choices that later turn out to be improvident." *Salazar ex rel. Salazar v. District of Columbia*, 633 F.3d 1110, 1120 (D.C. Cir. 2011) (internal citations and quotation marks omitted). Instead, Liquidia must wait for claim cancellation as the statute requires. *Supra* pp. 12-15, 22-23. Congress has "specifically acted" (*contra* RB30-32) by striking a balance between the Hatch-Waxman and IPR statutes, and "[c]ourts of equity cannot, in their discretion, reject the balance that Congress has struck in a statute." *United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 497 (2001); *see also Dunning v. United States*, 232 F. Supp. 915, 927 (W.D. Mo. 1964) ("We must presume that the Congress weighed

the equities when it wrote the statutes before us."), *aff'd*, 353 F.2d 940 (8th Cir. 1965).[6]

Liquidia's reliance on *Prism*, 757 F. App'x 980 (RB33), is misguided. The *Prism* court did not fault the defendant-appellee for dropping its invalidity defenses before trial because the liability judgment was still subject to direct review when the patent claims were invalidated in a parallel proceeding. *Id.* at 987. Indeed, "federal patent policy" counsels "against enforcing an unexecuted judgment of patent liability" when "the patent claims underlying that judgment have been held invalid by another decision having sufficient finality for this purpose; proceedings on direct review of the judgment have not yet been completed; and no agreement exists making portions of the judgment final." *Id.* Here, unlike in *Prism*, Liquidia moved for Rule 60(b) relief *after* the district court proceedings became final and this Court's mandate issued. *Supra* pp. 16-21; *see also Fresenius*, 721 F.3d at 1345-46. Liquidia made a calculated decision, and Rule 60(b) relief cannot undo the consequences Liquidia does not like.

[6] Liquidia asserts that the *Dunning* court was "citing a law review article, not statute or legislative history, where the author 'presume[d]' Congress weighed the equities." RB30-31 (alteration in original). That is unsupported by the plain text of the court's opinion.

Moreover, Liquidia's last-ditch effort to weigh equities does not, and cannot, warrant Rule 60 relief because the Hatch-Waxman Act guarantees mandatory, statutory relief to UTC until any potential cancellation of the '793 patent's claims. *See supra* pp. 12-15, 22-23. Nevertheless, Liquidia argues that it should be rewarded for "conserv[ing] judicial resources." RB34. Not so. Affirmance of the district court's decision would in fact breed more litigation because parties would be incentivized to file premature Rule 60 motions—*i.e.*, pre-claim cancellation—whenever claims that have been adjudicated valid and infringed are rendered unpatentable in a parallel PTAB proceeding, thus unnecessarily burdening the courts.

Liquidia further argues that "[i]f the district court's decision is not affirmed, Liquidia stands to be the only company precluded" by the '793 patent. RB34. That is an effort to obfuscate basic principles regarding Hatch-Waxman litigation. It is well-established that when a sponsor seeks FDA approval for a drug product that is protected by an Orange Book-listed patent, either by way of the new drug application pathway set forth in § 505(b)(2) or abbreviated new drug application pathway set forth in § 505(j) of the Federal Food, Drug, and Cosmetic Act, a patent

certification must be submitted with the sponsor's application. 21 U.S.C. §§ 355(b)(2)(A), (j)(2)(A)(vii). If the sponsor certifies that "such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted," (*id.* §§ 355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV)) the sponsor must also send notice to the patent owner. *Id.* §§ 355(b)(3)(C)(i), (j)(2)(B)(ii). Within 45 days of receiving such notice, the patent owner can—but is not required to—initiate infringement litigation. *Id.* §§ 355(c)(3)(C), (j)(5)(B)(iii). Because the '793 patent remains Orange Book-listed for UTC's Tyvaso® and Tyvaso DPI® products unless and until the claims of the '793 patent have been cancelled (*id.* § 355(j)(7)(D)), Liquidia is similarly situated to any other sponsor that wishes to market a generic or modified version of Tyvaso or Tyvaso DPI. In other words, all sponsors are equally subject to the patent certification and notice provisions of the Hatch-Waxman Act until any cancellation of the '793 patent claims, and thereby subject to a potential (but not certain) lawsuit for patent infringement.

CONCLUSION

The Court should reverse the district court's decision to grant Liquidia's motion for post-judgment relief under Federal Rule of Civil

Procedure 60(b), vacate the amended final judgment, and reinstate the original judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A).

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1) and Federal Circuit Rule 32(b)(3), the undersigned counsel for United Therapeutics Corporation certifies that this brief:

(i) complies with the type-volume limitation of Federal Circuit Rule 32(b)(1) because it contains 6,481 words, including footnotes and excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2); and

(ii) complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: July 8, 2024

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on July 8, 2024, the foregoing document was filed using the Court's CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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